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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/636,826	08/14/2000	Eike Duweing	50615	8623
26474	7590	04/20/2005	EXAMINER	
NOVAK DRUCE DELUCA & QUIGG, LLP			COLLINS, CYNTHIA E	
1300 EYE STREET NW			ART UNIT	
SUITE 400 EAST			PAPER NUMBER	
WASHINGTON, DC 20005			1638	

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/636,826

**Applicant(s)**

DUWEING ET AL.

**Examiner**

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 55,59,60,62-73,90,91,95 and 101-120 is/are pending in the application.
- 4a) Of the above claim(s) 101-120 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 62 is/are allowed.
- 6) ☒ Claim(s) 55,59,60,63-73,90,91 and 95 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed on February 4, 2005 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 7, 2005 has been entered.

Claims 1-54, 56-58, 61, 74-89, 92-94 and 96-100 are cancelled.

Claim 95 is currently amended.

Claims 101-120 are new.

Claims 55, 59-60, 62-73, 90-91, 95 and 101-120 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

### ***Election/Restrictions***

Newly submitted claims 101-120 are directed to an invention that is independent or distinct from the invention originally elected for the following reasons: claims 101-120 are directed to methods and products that require vulneration induced stress conditions, which conditions were not searched and examined as part of the originally elected invention.

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Since applicant has received an action on the merits for the originally elected invention, claims 101-120 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 95 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 95 is drawn to the method as claimed in claim 90 wherein at least one further pyrimidine stretch is inserted into the promoter of SEQ ID NO:1.

The specification describes the *B. vulgaris* V-ATPase subunit c isoform 2 set forth in SEQ ID NO:1, and plants cells transformed with a DNA construct comprising the *B. vulgaris* V-ATPase subunit c in isoform 2 promoter of SEQ ID NO:1 operatively linked with a heterologous gene that is a luciferase reporter gene (pages 22-23, 36 and 39-45). The specification does not describe DNA constructs comprising the *B. vulgaris* V-ATPase subunit c in isoform 2 promoter of SEQ ID NO:1 wherein at least one further pyrimidine stretch is inserted into the promoter.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that "A description of a genus of cDNAs may be achieved by

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means of recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1569; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

In the instant case Applicant has not described a representative number of species falling within the scope of the claimed genus which encompasses DNA constructs comprising the promoter of SEQ ID NO:1 wherein any number of pyrimidine stretches of unspecified sequence and length are inserted in any unspecified location into the promoter, nor the structural features unique to the genus.

Claim 95 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 95 is broadly drawn to the method as claimed in claim 90 wherein at least one further pyrimidine stretch of unspecified sequence and length is inserted at any unspecified location into the promoter of SEQ ID NO:1.

The specification discloses the *B. vulgaris* V-ATPase subunit c isoform 2 set forth in SEQ ID NO:1, and plants cells transformed with a DNA construct comprising the *B. vulgaris* V-ATPase subunit c in isoform 2 promoter of SEQ ID NO:1 operatively linked with a heterologous gene that is a luciferase reporter gene (pages 22-23, 36 and 39-45). The specification does not disclose how to make DNA constructs comprising the *B. vulgaris* V-ATPase subunit c in

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isoform 2 promoter of SEQ ID NO:1 wherein at least one further pyrimidine stretch is inserted into the promoter, or how to use said constructs to express a heterologous gene.

The claimed invention is not enabled because the effect of inserting at least one further pyrimidine stretch of unspecified sequence and length into any unspecified location of SEQ ID NO:1 is unpredictable.

See, for example, Acuto S. et al. (An element upstream from the human delta-globin-encoding gene specifically enhances beta-globin reporter gene expression in murine erythroleukemia cells. *Gene*. 1996 Feb 12;168(2):237-41), who describe the effect of 383-bp (delta383) and 99-bp (delta99) sequences containing the a pyrimidine-rich polypurymidine-binding factor (PYBF) binding site on transcription from various globin and non-globin promoters, using a transient assay with the cat reporter gene in murine erythroleukemia (MEL) cells, a cell line with abundant PYBF activity. Acuto S. et al. show that both delta383 and delta99 specifically enhance expression of cat for plasmids containing a human adult globin (HBB) promoter, whereas expression of similar constructs using human fetal (A gamma-) globin (HBG1) or simian virus 40 (SV40) promoters is not enhanced (page 240 Figure 3).

See also, for example, Becker N.A. et al. (Characterization of a polypurine/polypyrimidine sequence upstream of the mouse metallothionein-I gene. *Nucleic Acids Res*. 1998 Apr 15;26(8):1951-8), who investigated an approximately 190 bp fragment containing the 128 base pair long homopurine/homopyrimidine (R/Y) element obtained from the mouse metallothionein-I (MT-I) gene promoter to determine if it can influence transcriptional regulation. Becker N.A. et al. prepared promoter/reporter constructs in which the MT-I R/Y sequence was positioned in either orientation upstream of either the MT-I or HSV-TK promoters,

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and promoter/reporter activities were evaluated by transient transfection assays using mouse NIH3T3 cells. The MT-I R/Y sequence displayed no detectable activity as a cis -acting transcriptional regulatory element (page 1956 Figure 5).

See additionally, for example, Maiti A.K. et al. (Poly purine.pyrimidine sequences upstream of the beta-galactosidase gene affect gene expression in *Saccharomyces cerevisiae*. BMC Mol Biol. 2001;2(1):11. Epub 2001 Oct 8), who teach that beta-galactosidase gene expression is reduced 12-fold in cells carrying single copy poly purine.pyrimidine sequences inserted within a nucleosome positioned upstream of the beta-galactosidase gene in yeast between the cycl promoter and gal 10 Upstream Activating Sequences (UASg), and that this reduction in expression is correlated with reduced transcription (Figures 3 and 4).

In the instant case the specification provides no guidance with respect to the length or sequence of the at least one further pyrimidine stretch to be inserted into SEQ ID NO:1, or with respect to the location(s) in SEQ ID NO:1 to insert the at least one further pyrimidine stretch, in order to produce a promoter sequence with specific functional properties. Absent such guidance one skilled in the art would have to clone from unspecified sources or synthesize specific pyrimidine stretch sequences, and then test the effect of inserting those sequences into SEQ ID NO:1 in numerous different combinations and in numerous different locations, in order to discriminate between those promoter constructs that function as desired and those that do not. Such a trial and error approach to practicing the claimed invention would constitute undue experimentation.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 55, and claims 59-60 63-73 90-91 and 95 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 55 is indefinite in the use of parentheses. It is unclear whether the limitation within the parentheses is intended to limit the claim. It is suggested that the parentheses be deleted in order to overcome the rejection.

Claim 70, and claims 71-73 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 70 is indefinite in the recitation of "The transgenic plant", as there is insufficient antecedent basis for this limitation. It is suggested that the claim be amended to recite "A transgenic plant" in order to overcome the rejection.

***Remarks***

Claim 55, 59-60, 63-73, 90-91 and 95 are rejected.

Claim 62 is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins  
Examiner  
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CC

*Cynthia Collins* 4/15/05